

Insilico starts Phase 2 trial of AI-discovered fibrosis drug INS018_055

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Insilico Medicine's novel AI-generated small molecule inhibitor drug represents a new milestone in pharmaceutical drug development.

The world's first AI-generated anti-fibrotic small molecule inhibitor drug has been administered to the first human patients. Phase II clinical trials in the US and China are now underway for INS018_055, Insilico Medicine's potentially first-in-class oral drug candidate. Achievement of the first dose in human patients is a "milestone" for AI-driven drug discovery and drug development, stated Feng Ren, PhD, co-CEO and Chief Scientific Officer of Insilico Medicine. Initiating Phase II trials for an AI-generated drug The Phase II study will assess the safety, tolerability, pharmacokinetics and preliminary efficacy of 12-week oral INS018_055 dosage in subjects with the rare lung disease idiopathic pulmonary fibrosis (IPF). Patients will be divided into four parallel cohorts. To further evaluate the drug candidate in wider populations, the company plans to recruit 60 subjects with IPF at about 40 sites in both the US and China.

In early 2023, INS018_055 received positive topline data in Phase I. The small molecule inhibitor was dosed in 78 and 48 healthy subjects, divided into cohorts focusing on a single ascending dose (SAD) study and multiple ascending dose (MAD) study. The international multi-sites Phase I studies demonstrated consistent results, indicating favourable safety, tolerability of the AI-generated INS018_055. The observed human PK of INS018_055 showed no significant accumulation after seven days and exhibited a favourable PK profile. INS018_055 was generally safe and well tolerated by healthy volunteers in the study. This data supported the initiation of the Phase II study. "With demonstrated potential against both fibrosis and inflammation, INS018_055 could offer another option for patients worldwide," commented Ren. The company first described the concept of using generative artificial intelligence for the design of novel molecules in a peer-reviewed journal in 2016. In February 2021, the small molecule drug INS018_055 started a first-in-human study for IPF in November 2021. The US Food and Drug Administration (FDA) granted Orphan Drug Designation to INS018_055 for the treatment of IPF in February 2023. FDA publishes paper on AI/ML in drug development

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